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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/113,924	07/09/1998	DAVID R. BRIGSTOCK	08766/003002	8612

28213 7590 03/20/2009

DLA PIPER LLP (US)
4365 EXECUTIVE DRIVE
SUITE 1100
SAN DIEGO, CA 92121-2133

EXAMINER	
SPECTOR, LORRAINE	
ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
03/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/113,924	BRIGSTOCK ET AL.	
	Examiner	Art Unit	
	/Lorraine Spector/ Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2005 and 1/16/2009* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application was revived in a petition granted 10/5/2005. This action is in response to the amendment filed 7/25/2005. Claims 1-7 have been cancelled, claims 8-14 are pending. They do not introduce new matter, although there have been no previous claims to an antibody that specifically binds SEQ ID NO: 2.

It is noted that SEQ ID NO: 2 corresponds to residues 248-259 of SEQ ID NO: 2 of U.S. Patent No. 5,408,040 with the exception that Xaa in the instant sequence is actually a string of five residues in the patented sequence.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8 and 14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are broadly drawn to polyclonal antibodies that bind to any heparin binding growth factor polypeptide. As such polypeptides occur in nature, the person of ordinary skill in the art would reasonably expect antibodies to such also to occur. Accordingly, the claims are drawn to products of nature.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is indefinite as the word "has" has no clearly defined meaning as drawn to an amino acid sequence; it might mean "consists of", or alternatively "comprises". Claims 11 and 12 are similarly indefinite.

Claims 13 and 14 are indefinite because an antibody cannot be a fragment of itself, i.e. a monoclonal antibody cannot be an antibody fragment.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8-14 are provisionally rejected on the ground of nonstatutory double patenting over claims 15, 19 and 21 of copending Application No. 10/658856. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: SEQ ID NO: 4 of the '856 application corresponds to residues 179-348 of CTGF. Accordingly, SEQ ID NO: 2 falls within that fragment.

As that portion of CTGF inherently binds heparin, claim 8 is clearly anticipated. As stated above with respect to claim 9, the term "has" is indefinite and can be reasonably interpreted as meaning "comprises". As the CTGF of the '856 application appears to differ from that of the instant application only by the insertion in SEQ ID NO: 4 (which is the same as that of SEQ ID NO: 2 of the '040 patent), the molecule of the issued patent clearly comprises that of the instant SEQ ID NO: 2. With respect to claim 10, since the claims are drawn to antibodies and not polypeptides, antibodies to the fragment of the copending application would meet the claim limitations. Further, the antibodies of the copending application would inherently include antibodies that would bind to fragments of 10-20 kD, as the fragement therein falls into that mass range.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 8, 10, 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Jaye et al., U.S. Patent No. 4,868,113.

Jaye et al. teach DNA encoding human endothelial cell growth factor (ECGF). One of the cited references, Maciag et al., is entitled "Heparin binds Endothelial Cell Growth Factor, the Principal Endothelial Cell mitogen in Bovine Brain". Accordingly, ECGF is a heparin binding growth factor. At column 1, second paragraph, it is stated that ECGF has an apparent molecular

weight of 20,000 daltons (20 kDa) (line 29), and by another method two species were obtained, having molecular weights of 17, 000 and 20,000 daltons, thus meeting the limitation of claim 10. At column 13, first full paragraph, are disclosed rabbit anti-ECGF antibodies, and murine monoclonal anti-ECGF antibodies. It is not specified whether the rabbit antibodies were monoclonal or not. However, the person of ordinary skill in the art is well aware that it is necessary to first make polyclonal antibodies (at least at the time Jaye's invention was made) to make monoclonal antibodies. Accordingly, the claims are anticipated by Jaye et al.

Claims 8-14 are rejected under 35 U.S.C. 102(e) as being anticipate by U.S. Patent No. 5,795,862 (Frank et al.).

Frank et al. disclose a SEQ ID NO: 31, which is a 6/7 match to SEQ ID NO: 2, varying only at the c-terminus of SEQ ID NO: 2. The alignment of the two sequences is shown in the appendix to this Office Action. SEQ ID NO: 31 has a total length of 25 residues and the match is at residues 3-9, near the N-terminus, and therefore expected to be available as an antigen. The protein of SEQ ID NO: 31 is specifically claimed. The fragment is disclosed as being from Ectoparasite saliva proteins. Antibodies are disclosed at column 4, lines 16-18. At column 45, beginning at line 28, it is stated that antibodies to the proteins may be monoclonal or polyclonal. Claim 9 introduces the limitation that the antibody binds specifically to an amino acid sequence a set forth in SEQ ID NO: 2. Claims 11 and 12 further limit to residues 247 or 248-329 of human CTGF. Given the similarity to the fragment of Frank et al., it would be expected that Frank's antibodies would meet these limitations. However, the Examiner, lacking laboratory facilities, is unable to determine such unequivocally. Since the Office does not have the facilities for examining and comparing applicants' antibodies with the antibodies of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Claims 8-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Grotendorst et al., U.S. Patent No.5,408,040.

The '040 patent claims antibodies to the CTGF polypeptide of SEQ ID NO: 2 therein, but not to PDGF, wherein said antibodies may be polyclonal or monoclonal; see claims 2-4. As CTGF inherently binds heparin, claim 8 is clearly anticipated. As stated above with respect to claim 9, the term "has" is indefinite and can be reasonably interpreted as meaning "comprises". As the CTGF of the '040 patent appears to differ from that of the instant application only by the extra five residues in SEQ ID NO: 2 of the issued patent, the molecule of the issued patent clearly comprises that of the instant SEQ ID NO: 2 (with an internal insertion). With respect to claim 10, since the claims are drawn to antibodies and not polypeptides, and the meaning of "has" and "having" is in question, antibodies to the full-length protein would meet the claim limitations. Further, as the '040 patent teaches at paratraph DETX (19) that antibodies may be made to fragments of CTGF, such would inherently include antibodies that would bind to fragments of 10-20 kD. There is no reason that the antibodies of the '040 patent would not bind to fragments of CTGF having molecular weights of 10-20 kDa. Similarly, full-length CTGF comprises residues 247-349 such that the limitations of claim 12 are met.

Accordingly, the claims are anticipated by the '040 patent.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Dr. Manjunath Rao, at telephone number 571-272-0939.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to **571-273-8300**. Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lorraine Spector/ , Ph.D.
Primary Examiner
Art Unit 1647

Appendix- Sequence Alignments

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RESULT 5
US-08-487-001A-31
; Sequence 31, Application US/08487001A
; Patent No. 5795862
;  GENERAL INFORMATION:
;    APPLICANT:  FRANK, GLENN R.
;    APPLICANT:  HUNTER, SHIRLEY WU
;    APPLICANT:  WALLENFELS, LYNDA
;    TITLE OF INVENTION:  NOVEL ECTOPARASITE SALIVA
;    TITLE OF INVENTION:  PROTEINS AND APPARATUS TO COLLECT SUCH PROTEINS
;    NUMBER OF SEQUENCES:  54
;    CORRESPONDENCE ADDRESS:
;      ADDRESSEE:  Sheridan Ross & McIntosh
;      STREET:  1700 Lincoln Street, Suite 3500
;      CITY:  Denver
;      STATE:  Colorado
;      COUNTRY:  U.S.A.
;      ZIP:  80203
;    COMPUTER READABLE FORM:
;      MEDIUM TYPE:  Floppy disk
;      COMPUTER:  IBM PC compatible
;      OPERATING SYSTEM:  PC-DOS/MS-DOS
;      SOFTWARE:  PatentIn Release #1.0, Version #1.25
;    CURRENT APPLICATION DATA:
;      APPLICATION NUMBER:  US/08/487,001A
;      FILING DATE:  07-JUN-1995
;      CLASSIFICATION:  424
;    ATTORNEY/AGENT INFORMATION:
;      NAME:  Verser, Carol Talkington
;      REGISTRATION NUMBER:  37,459
;      REFERENCE/DOCKET NUMBER:  2618-17-C2
;    TELECOMMUNICATION INFORMATION:
;      TELEPHONE:  (303) 863-9700
;      TELEFAX:  (303) 863-0223
;  INFORMATION FOR SEQ ID NO:  31:
;    SEQUENCE CHARACTERISTICS:
;      LENGTH:  25 amino acids
;      TYPE:  amino acid
;      TOPOLOGY:  linear
;    MOLECULE TYPE:  protein
US-08-487-001A-31

  Query Match             58.2%;  Score 32;  DB 1;  Length 25;
  Best Local Similarity   85.7%;  Pred. No. 88;
  Matches    6;  Conservative    1;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 ENIKKGK 7
              |||||| :
Db          3 ENIKKGE 9
```